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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/622,146 | 01/02/2001 | Rolando Barbucci | 515-4204 | 8284 |

7590 09/04/2002
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EXAMINER

SERGEANT, RABON A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1711

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/622,146

Applicant(s)
Barbucci et al.

Examiner
Rabon Sergent

Art Unit
1711



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 24, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al. ('865) in view of WO 95/25751 and Halpern et al. ('114).

Balazs et al. disclose the covalent bonding of hyaluronic acid to polyurethane and the use of such materials in medical applications. See example 3.

3. Balazs et al. are silent regarding the sulphate modification of the hyaluronic acid component; however, sulphated hyaluronic acids and their use with polyurethanes and within medical applications was known in the art at the time of invention. This position is supported by

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the teachings of WO 95/25751. See entire document and especially line 20 of page 28. Furthermore, the covalent bonding of polysaccharides, including sulphate containing polysaccharides, to substrates, including isocyanate group containing substrates, to produce medical articles was known at the time of invention. See abstract; figures; and column 4, lines 20+ within Halpern et al.

4. In view of the teachings within Halpern et al. regarding the bonding of sulphate polysaccharides to isocyanate containing substrates, the position is taken that it would have been obvious to utilize the sulphated hyaluronic acids of WO 95/25751 as the hyaluronic acid component of Balazs et al., so as to arrive at the instant invention.

5. The examiner has considered applicants' arguments of September 10, 2001. Applicants have argued, firstly, that Balazs et al fail to disclose covalently bound hyaluronic acid. However, this argument is flawed; Balazs et al. clearly disclose the covalent bonding of hyaluronic acid to polyurethane within example 3. Secondly, applicants have argued that it could not have been predicted that sulphated hyaluronic derivatives would retain their anti-coagulant properties if they were covalently bound to a polyurethane. In response, obviousness does not require absolute predictability. *In re Miegel*, 159 USPQ 716. In the instant case, Halpern et al. disclose the covalent bonding of sulphated polysaccharides to substrates, including isocyanate containing substrates, wherein the sulphated polysaccharides have similar utilities and structures to the sulphated hyaluronic acids of WO 95/25751. Since sulphated compounds were used within

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Halpern et al., one would have reasonably expected that analogous compounds, such as the sulphated hyaluronic acids of WO 95/25751, could also be covalently bound without losing the advantages conveyed by the sulphate groups. Applicants have provided no evidence that one of ordinary skill would have expected that sulphated hyaluronic acids, when covalently bound, would lose the characteristics attributable to the sulphate groups. Lastly, the position is taken that the substrates of Halpern et al. are comparable to polyurethanes, if not actually met by polyurethanes, given the use of the isocyanate compounds. Isocyanates are a key component within urethane chemistry.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (703) 308-2982.

R. Sergent
September 3, 2002


RABON SERGENT
PRIMARY EXAMINER